IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Susan J. WONG et al.
Serial No.	:	10/699,550
Filing Date	:	October 31, 2003
Title	:	DIAGNOSTIC TEST FOR WEST NILE VIRUS
Examiner	:	Sharon L. Hurt
Art Unit	:	1648

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DECLARATION UNDER 37 C.F.R. §1.132

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

WE, SUSAN J. WONG AND PEI-YONG SHI, declare and state that:

1. We are the named inventors on the above captioned application (hereinafter "the present application") and are familiar with its prosecution history, including the Office Action mailed on February 22, 2006.

2. We, Susan J. Wong and Pei-Yong Shi, respectfully submit that we are experts in the field of serodiagnostic assays. Brief curricula vitae are attached as Appendices A and B. We have both been active researchers in this field for more than 6 years and, together and separately, have published more than 80 relevant primary articles in peer-reviewed journals and more than 8

review articles and contributions to books. We have obtained very substantial external research funding for our work in this area in open competition. We both lead research groups within Wadsworth Center in which we supervise more than 19 full-time research staff who are investigating aspects of diagnostic serology of human infections. We are both regularly asked to speak to the subject of serodiagnostic assays at national and international scientific meetings.

3. Accordingly, in view of our education, training and experience, we are considered by our peers to be experts in the field to which the present application pertains, and qualified to knowledgeably characterize the art to which the invention in the present application relates, and to speak as to the present application, and the invention claimed, including being qualified to present expert opinions about the present invention and literature in support of it, and documents cited against the present invention. Moreover, we respectfully submit that we are qualified to state the knowledge in the art, and that which would have been obvious and nonobvious to the skilled artisan.

4. It is our understanding that the Examiner rejected claims 74, 76-105, 126-128, 145, 156, and 162-202 under 35 U.S.C. §103(a) as being obvious over references Wang *et al.* ("Wang"), Valdes *et al.* ("Valdes"), Mandy *et al.* ("Mandy"), Scaramozzino *et al.* ("Scaramozzino"), and McDonell *et al.* ("McDonell").

5. More in particular, we were advised that in the February 22, 2006 Office Action, these claims were rejected because the Examiner believed that it would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the teaching of Wang, Valdes and Mandy to use West Nile virus (WNV) recombinant nonstructural protein 5 (NS5) protein to detect WNV infections in humans and horses; that a person of ordinary skill in the art would have been motivated to use the NS5 and E proteins as immunodiagnostic assays for the detection of WNV in biological samples; that McDonell teaches a diagnostic kit with an immunogenic composition using ELISA and fluorescent labeling; and that one would have expected success because of the teachings of Scaramoizzino who developed a rapid, sensitive PCR assay for the detection of flavivirus with NS5 gene sequences.

6. The recombinant NS5-based microsphere immunoassay of the present application is an assay for detection of human or equine WNV infection that is useful for (i) differentiating between WNV infection and dengue (DEN) virus or St. Louis encephalitis (SLE) virus; (ii)

differentiating between flavivirus vaccination and natural WNV infection; and (iii) indicating recent WNV infections.

7. The assay of the present invention was initially disclosed in Wong, S.J. *et al.*, Immunoassay Targeting Nonstructural Protein 5 to Differentiate West Nile Virus Infection from Dengue and St. Louis Encephalitis Virus Infections and from Flavivirus Vaccination, Journal of Clinical Microbiology, Sept. 2003, p. 4217-4223 (hereinafter, "Wong *et al.*"). Wong *et al.* was cited on the Information Disclosure Statement, form PTO-1449, filed March 7, 2005. The Journal of Clinical Microbiology is a peer-reviewed journal.

8. The assay of the present invention is a highly sensitive diagnostic method for differentiating between flaviviral infections. This method works repeatedly.

9. Prior to the publication of Wong *et al.*, such a highly sensitive method did not exist. This high sensitivity is due in part to the NS5 of WNV being covalently attached via its amino terminus to the surface of polystyrene microspheres. A suspension phase immunoassay using these microspheres is most specific for West Nile virus and only minimally cross reactive in sera from patients with other flavivirus infections. Moreover, the assay has a very low amount of non-specific reactions from other clinical conditions. In addition, until Wong *et al.*, the use of the West Nile recombinant NS5 as a diagnostic target (antigen) had not been demonstrated for specific detection of West Nile antibodies or, indeed, for the specific detection of *any* flavivirus. Even today, most flavivirus assays are based upon killed virus, extracted from cell cultures or infected suckling mouse brain. Others are based on non-infectious viral particles comprised principally of the envelope protein that induces broadly cross-reactive sera.

10. At the time of filing of the present application, the state of the art did not teach or suggest to one of skill in the art that recombinant NS5 could be used with the Luminex platform to arrive at the present invention. The reviewers of the Wong *et al.* manuscript had the following comments:

- REVIEWER 1: This paper provides data which may lead the way to the solution of a problem which has confounded and burdened the serologic diagnosis of flavivirus infection, e.g., cross reactivity.
- REVIEWER 2: The manuscript by Wong *et al.* describes a serological test for WNV infection based on an E. coli-expressed form of NS5. In the assay format

presented, this form of NS5 appears to be useful for distinguishing among infections with different flaviviruses.

11. The assay of the present invention has been shown by us to be useful for the detection of antibodies to WNV in the sera of vaccinated and naturally infected horses. This data was disclosed in Udeni, B.R. *et al.*, Detection Of Antibodies To West Nile Virus In Equine Sera Suing Microsphere Immunoassay, J. Vet. Diagn. Invest. 18:392-395 (2006). Table 2, (page 194, left column), shows that the NS5 microsphere immunoassay had 100% specificity in equine sera.

12. There exist various other technologies that could possibly be applied to use of NS5, however at the time of filing the present application none of these had been demonstrated to be effective strategies. Based on our knowledge and skill, we believed that there was a likelihood that assay strategies based upon passive adsorption to surfaces might not introduce the epitope of NS5 in a conformation and manner necessary for recognition of West Nile antibodies.

13. In November 2004, Focus Diagnostics investigated the use of the WNV recombinant NS5 antigen, provided by us, for use in an ELISA format for the detection of NS5 antibodies in serum panel from WNV patients. An indirect ELISA using NS5 coated plates was used to detect IgG, and an IgM capture format was used to detect IgM. The IgM capture ELISA used an anti-NS5 monoclonal antibody to detect NS5 antigen bound to IgM captured on the plate. The serum panel consisted of 110 sera previously characterized for the presence of antibodies to the WNV pre M/E recombinant protein. For the detection of IgG antibody, very weak reactivity was noted. Regardless of the NS5 coating concentration, no signal above an optical density (OD) (450nm) of 0.5 was found, and only 5 of 25 WNV IgG positive samples gave an OD between 0.3 and 0.5. All other samples in the serum panel had ODs less than 0.25. The detection of NS5 IgM positive samples was not possible with the reagents supplied. Accordingly, based on these results, of indirect IgG ELISA, the NS5 antigen did not show much reactivity with patient samples that were IgG positive on the Luminex platform. This low reactivity indicates that NS5 antigen coated onto plates could not discriminate true IgG positive samples from IgG negative samples. Furthermore, attempts to use NS5 antigen on IgM capture ELISA format was not successful since the monoclonal anti-NS5 antibody that was available for use did not show binding activity with NS5 antigen coated onto ELISA plates. The failure of other assays, it is clear, is due to the structure and properties of the NS5 protein rather than to human error.

14. Other than the luminex platform claimed in the present application, which work well repeatedly, there are no methods of rapidly diagnosing against WNV and discriminating West Nile virus from other flavivirus infections.

15. We further declare that statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signature: Susan J Wong Date: 2/16/07
Susan J. WONG

Signature: Peiyong Shi Date: 2/16/07
Pei-Yong SHI

CURRICULUM VITAE

Susan J. Wong

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CITIZEN:

USA and Canada

EDUCATION:

University of Saskatchewan	Biochemistry	Ph.D. 1980
University of New Hampshire	Biochemistry	M.Sc. 1972
University of Wisconsin	Molecular Biology	B.Sc. 1969

CERTIFICATION AND REGISTRATION:

Diplomate (No.80)	American Board of Medical Laboratory Immunology	1985
	Recertified	1998-2001
	Recertified	2001-2004
	Recertified	2004-2007
RT	Canadian Society of Laboratory Technologists	1976
Certificate of Qualification	New York State Department of Health (Diagnostic Immunology, Histocompatibility, Bacteriology-Molecular Techniques)	2002 -2004

MEMBERSHIP:

American Society for Microbiology
American Society for Rickettsiology
American Society for Tropical Medicine and Hygiene
Infectious Diseases Society of America
International Conference on Diseases in Nature Communicable to Man (President 2004 – 2005)

HONORS AND AWARDS

1999 Wadsworth Center Recognition Award
2000 NYSDOH Commissioner's Recognition Award – West Nile Virus Response
2002 Charles Shepard Science Award Nominee from CDC, USPHS
2003 Thomas Nakano Commendation from CDC, USPHS
2004 NYSDOH Commissioner's Recognition Award – SARS Response

PROFESSIONAL AND RESEARCH EXPERIENCE:

Wadsworth Center New York State DOH Albany, New York	Research Scientist 6, Director Diagnostic Immunology, and Proficiency Testing (for DI and HIV)	Dec. 94 - Present
State University of New York at Albany	Assistant Professor Biomedical Sciences	Jan. 96 - Present
Regional Laboratory Red Deer Regional Hospital Centre Red Deer, Alberta, Canada	Clinical Specialist Immunology	1991 - 1994
Smith-Kline Beecham Clinical Laboratories Van Nuys, California	Manager, Immunology BioScience Laboratory	1991 (Mar to Aug)
Foothills Hospital Calgary, Alberta, Canada	Clinical Laboratory Immunologist	1988 - 1991
Foothills Hospital Calgary, Alberta, Canada	Laboratory Scientist Immunology	1982 - 1988
University of Calgary	Postdoctoral Fellow Medical Biochemistry	1980 - 1982
University of Liverpool United Kingdom	Postdoctoral Fellow Biochemistry	1980
University of Saskatchewan	Graduate Student Biochemistry Veterinary Physiology Dept.	1975 - 1980
	Technician (Research) Medicine and Pathology	1972 - 1975
University of New Hampshire	Graduate Student Biochemistry	1970 - 1972

Univ. of Rochester (NY) and Univ. of Minnesota (Mpls.)	Research Technician	1969 - 1970

Grants and External Funding (Current and Recent)

US Based Collaboration in Emerging Viral and Prion Diseases
September '04 – September 05, ($15,000/yr) Collaborator
NIAID/NIH

Emerging Infections Program – Supplemental Surveillance of Human Granulocytic Ehrlichiosis. CDC/US PHS
Develop specific immunoassay for He and other tick-borne diseases
December '03 – December '04 ($112,000/yr) PI

Enhanced Laboratory Capacity for West Nile Virus CDC
Development of Diagnostic Assays for Human Infection by WNV.
April ' 01 – April' 04 ($100,000/yr) Dr. Dale Morse, PI.

Proposals Submitted (not funded)

Proposal Submitted (October 15, 2000). "Research on the Laboratory Diagnosis and Pathogenesis of Lyme Diseases in the United States" to CDC for Cooperative Agreement. Program Announcement 01-005.

Three SBIR proposals to NIH and DOD (from Inter Science Inc with subcontract to Wadsworth) for Miniaturization of Laboratory Systems ("Lab-on-a-Chip") submitted 1996, 1997.

Two SBIR proposals to NIH (with L Squared Diagnostics) on Tularemia (2002) and dengue fever (2004).

Contracts and Subcontracts Awarded

Year	Company	Amount	Topic
1997	Cambridge Diagnostics	$2,076	Lyme Disease Assay
1999	Copalis Dia Sorin	$7,973	Rubella Assay
2002	Abbott Laboratories	$4,000	West Nile Assay
2002	NIAID	$15,000	West Nile Assay
2003	Focus Technologies	$17,500	West Nile Trial Site
2005	Spectral Diagnostics	$13,095	West Nile Trial Site

Patents

United States Provisional Application 6/422, 755 filed October 31, 2002. (Susan J. Wong) "Diagnostic Test for West Nile Virus"

United States Provisional Application 454311-2260 Reference Number filed June 6, 2003. (Susan J. Wong and Pei Yong Shi). "Diagnostic Test for West Nile Virus.

Recent Workshop and Meeting Participation (2004-2006)

2006 American Society of Retina Specialists, September 7-14, 2006. Cannes France.

2006 International Conference on Disease in Nature Communicable to Man. August 6-9, 2006. San Antonio, TX.

2006 National West Nile Virus Conference. February 22-24, 2006. San Francisco, CA.

2005 American Society of Tropical Medicine & Hygiene. December 11-14, 2005. Washington, DC.

2005 60th Annual International Conference on Diseases in Nature Communicable to Man. August 7-9, 2005, Calgary, Alberta, Canada.

2005 American Society of Microbiology – Eastern New York Branch. New technologies in microbiology. March 7, 2005, Albany Medical Center, Albany, NY.

2005 West Nile Virus Review and planning meeting (Public Health Agency of Canada). Jan 10-11, 2005. Ottawa, Ontario, Canada.

2005 National Conference on West Nile Virus in the United States. Feb 8-9, 2005. San Jose, CA.

PAPERS PUBLISHED (Also under S.J. Johnson, S.J. Bagley)

1. Gardner, I.A, S.J. Wong, G.L. Ferraro, U.B. Balasuriya, P.J. Hullinger, W.D. Wilson, P.Y. Shi, N.J. MacLachlan. Incidence and Effects of West Nile Virus Infection in Vaccinated and Unvaccinated Horses in California. Vet. Res. 38 (2007) 109-116.

2. Beer, P.M, S.J. Wong, A.M. Hammad, N.S. Falk, M.R. O'Malley. Vitreous Levels Of Unbound Bevacizumab And Unbound Vascular Endothelial Growth Factor In Two Patients. Retina. 2006. 26:871-876.

3. Balasuriya, U.B., P.Y. Shi, S.J. Wong, V.L. Demarest, I.A. Gardner, P.J. Hullinger, G.L. Ferraro, J.D. Boone C.L. De Cino, A.L. Glaser, R.W. Renshaw, M. Ledizet, R.A. Koski, and N.J. MacLachlan. Detection of antibodies to West Nile virus in equine sera using microsphere immunoassay. J Vet Diagn Invest. 2006 July 18 (4): 392-5.

4. Nguyen, Q., S. Teran, J. Snedeker, C.B. Morrow, C. Huang, W. Wong, B. Wallace, L.F. Novick. CNS Sequelae in an Infant with Congenital West Nile Virus Infection. Infections in Medicine. Dec. 2005. pp. 626-628.

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6. De la Fuente, J., R.F. Massung, S.J. Wong, F.K. Chu, H. Lutz, M. Meli, F.D. von Loewenich, A. Grzeszczuk, A. Torina, S. Caracappa, A.J. Mangold, V. Naranjo, S. Stuen, and K.M. Kocan. Sequence Analysis of the msp4 Gene of Anaplasma phagocytophila Strains. 2005. Journal of Clinical Microbiology 43:1309-1317.

7. Kumar, D., M.A. Drebot, S.J. Wong, G. Lim, H. Artsob, P. Buck, and A. Humar. 2004. A Seroprevalence Study of West Nile Virus Infection in Solid Organ Transplant Recipients. Am J. Transplantation. 4:1296-1301.

8. Wong, S.J., V.L. Demarest, R.H. Boyle, T. Wang, M. Ledizet, K. Kar, L.D. Kramer, E. Fikrig, and R.A. Koski. 2004. Detection of Human Anti-Flavivirus Antibodies with a West Nile Virus Recombinant Antigen Microsphere Immunoassay. J. Clin. Microbiol. 42:65-72.

9. Shi, P.-Y. and Wong, S.J. 2003. Serologic Diagnosis of West Nile virus infection. Expert Rev. Mol. Diagn. 3(6):89-97.

10. Wong, S.J., R. H. Boyle, V. L. Demarest, A. N. Woodmansee, L.D. Kramer, H. Li, M. Drebot, R. A. Koski, E. Fikrig, D. A. Martin, and P.-Y. Shi. 2003. Immunoassay Targeting Nonstructural Protein 5 to Differentiate West Nile Virus Infection from Dengue and St. Louis Encephalitis Virus Infections and from Flavivirus Vaccination. J. Clin. Microbiol. 41:4217-4223.

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19. Wong SJ and SJ Seligman. 2001. Long Term Stability of West Nile Virus IgM and IgG Antibodies in Diluted Sera Stored at 4 C. Ann NY Acad. Sciences. 951: 369-372.

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24. CDC (S. Wong, "reporter"). 1999. Update: West Nile Virus. Encephalitis-New York, 1999. MMWR. 48:944-946, 955.

25. CDC (S. Wong, "reporter"). 1999. Update: West Nile-Like Viral Encephalitis-New York, 1999. MMWR 48:890-892.

26. CDC (S. Wong, "reporter"). 1999. Outbreak of West Nile-Like Viral Encephalitis-New York, 1999. MMWR 48: 845-849.

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36. Shiozawa, C.*-, Adachi, M.*, Kashiwagi, N.*-, Hayamo, M.+, Mizuta, T.*, Ohta, Y.+, Gill, M.J.-, Matheson, D.S.-, Tamaoki, T-, Ohnishi, M*-, Johnson, S.-, and Hakomori, S.# (Japan Immunoresearch Lab, Takasaki, Japan*; Inst. of Med. Sci., Univ. of Tokyo, Minato-ku Japan+; Faculty of Medicine, Univ. of Calgary, Ab., Canada; Dept. of Pathology, Univ. of Washington, Seattle, W.A., U.S.A.#. Carbohydrate Antigen Expression of HIV Infected Human Lymphocytes. Proceeding of KAGOSHIMA International Symposium of Glycoconjugates in Medicine (1990).

37. Johnson, S.J., Gupta, V.S., Stevenson, K.J., and Frieisheim, J.H., Purification and characterization of dihydrofolate reductase from Walker 256 carcinosarcoma. Can. J. Biochem., 60, 1132-1142 (1982).

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41. Sargent, A.U., S.J. Johnson and A.K. Richardson. Isolation and functional purification of the first seven components of canine hemolytic complement. Immunochemistry 13 (10), 823-829 (1976).

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ABSTRACTS

1. Wong, S.J., P.M. Beer. Suspension Phase Microsphere Immunoassay of Bevacizumab Levels in Ocular Fluids and Sera. American Society of Retinal Specialists, Cannes France. September 7-14, 2006.

2. Wong, S.J., L.D. Kramer, G.D. Ebel. Powassan Encephalitis. International Conference on Diseases in Nature Communicable to Man. International Conference on Diseases in Nature Communicable to Man. San Antonio, TX. August 6-9, 2006.

3. Wong, S.J., U.B. Balasuriya, P-Y Shi, I.A. Gardner, P.J. Hullinger, G.L. Ferarro, J.D. Boone, C.L. DeCino, V.L. Demarest, A.L. Glaser, R.W. Renshaw, M. Ledizet, R.A. Koski, N.J. MacLachlan. Equine Antibody Responses to West Nile Virus Infection and Vaccination: Multiplex Microsphere Immunoassay with structural and Nonstructural Viral Proteins Compared to Plaque Reduction Neutralization. Annual West Nile Virus Conference. San Francisco, CA. February 22-24, 2006.

4. Campbell, M.M., S.J. Wong, E. Bell, S. Gohel, J. Paley, E. DeBernardo, A. Fine. False Positive West Nile IgM ELISA Tests in Outpatients with Febrile Illnesses, New York City, 2005. Annual West Nile Virus Conference. San Francisco, CA. February 22-24, 2006.

5. Wong, S.J., A.P. Dupuis II, A.M. Kilpatrick, P.P. Marra, A.L. Glaser, T. Victor, P. Daszak, L.D. Kramer. Comparison of Indirect ELISA and Plaque Reduction Neutralization to Multiplex Microsphere Immunoassay for Detection of Antibodies to West Nile Virus in Blood of Wild Birds. American Society for Tropical Medicine & Hygiene. 54th Annual Meeting, Washington, DC. December 11-14, 2005.

6. Wong, S.J., F. Chu, K. Kulas, J. S. Dumler, L. Berrada, S. Hennigan, D. Katz, B. Matyas, D. Pereira, S. Soliva, V. Berardi, K. Weeks, E. Fikrig. Laboratory Investigation of Human Granulocytic Anaplasmosis in the Housatonic River, River Valley, Berkshire County, Massachusetts 2004. International Conference on Diseases in Nature Communicable to Man, Calgary, Alberta, Canada. August 7-9, 2005.

7. Wong, S.J., M. Behr, F. Chu, V. Demarest, E. Fikrig, N. Ramamoothi, Y.-F. Chang, D. Lawrence. Multiplex Microsphere Immunoassay (MIA) for the Detection of Antibodies to Recombinant Proteins Derived from *Borrelia burgdorferi* and I*xodes scapularis* Saliva in Retrievers with Lyme Borreliosis Associated Glomerulonephritis (GN). International Conference on Diseases in Nature communicable to Man. Calgary, Alberta, Canada. August 7-9, 2005.

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44. Susan J. Wong, Rory A. Duncan, and Geraldine S. Brady. Lyme Disease Serology from Human Granulocytic Ehrlichiosis Cases from New York State. American Society for Rickettsiology and Rickettsial Diseases, Pacific Grove, California, May 1996.

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55. Toshinobu Mizuta, Masakazu Adachi, Takashi Kosedo, Katsuuki Nakajima, Kunikazu Akutsu, J.A. Williamson, Nobuhito Kashiwagi, Mamoru Ohnishi, Chiaki Shiozawa, Taiki Tamaoki, M.J. Gill, T. Bowen, M.-C. Poon, D.S. Matheson, S. Johnson1, D. Church, Kazuko Handa, Sen-Ichiro Hakomori, Yoshihiro Ohta, Masanori Hayami. Expression of Carbohydrate Antigen on HIV Infected Cells. III. The expression of Ley antigen and the change of host cells. 1st AIDS Research Meeting in Japan. Kyoto Calkin, Univ. of Kyoto, Kyoto, Japan. December 21-22, 1987.

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57. S.J. Johnson and M.J. Fritzler. Partial purification and characterization of proliferating cell nuclear antigen (PCNA). Abstract #337. Royal College of Physicians and Surgeons of Canada. Fiftieth Annual Meeting, Toronto, Ontario. September, 1981.

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59. S.J. Johnson and V.S. Gupta. Dihydrofolate reductase of Walker carinoma. Purifications and Properties. Can. Fed. Proc., 20: #221, 1977.

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61. S.J. Johnson and J.A. Stewart. Regulation of protein and RNA synthesis during postnatal development of the mouse brain. Proc. C.F.B.S. 16, #165, 1973.

62. A. Sargent, S. Johnson, Y. Yong. Functional incompatibility existing between C2 component of dog complement and guinea pig C5. Proc. C.F.B.S. 16, #443, 1973.

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Published Presentations on the Web

1. http://www.fda.gov/cber/minutes/wnv110402.pdf. Detection of Human Antibodies to West Nile Virus with a recombinant Antigen Microsphere Immunofluorescence Assay. Pp.66-83.

2. http://www.cdc.gov/ncidod/dvbid/westnile/conf/march_2002.htm. West Nile Virus Serology MRL IFA versus ELISA and New Technologies. Breakout Session 2, Lab Diagnosis.

Biomedical Sciences SUNYA School of Public Health

1. Lectures in three courses annually (Introductory Immunology, Biological Basis of Public Health, Epidemiology of Infectious Diseases) with a total of about 6 lectures given.

2. Current member of the Admissions Committee for professional programs (MPH, DrPH) at SPH. Past member of the Personnel Committee.

3. Previous mentor for SUNYA undergraduate research projects, REU students, CDCEIP fellows.

4. Previous host/mentor for visiting scientists from Taiwan, Canada, Maine, Pennsylvania. Florida, Washington and other locales.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Shi, Pei-Yong	Research Scientist/Assistant Professor
eRA COMMONS USER NAME Pei_Yong_Shi	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Nanjing Normal University, China	B.S.	1989	Biochemistry
Georgia State University, Atlanta, GA	Ph.D.	1995	Molecular Virology
Yale University School of Medicine, New Haven, CT	Postdoc.	1998	Biochemistry

A. Positions and Honors

Positions and Employment

1992-1995 Research Assistant, Ph.D. program in molecular virology, Department of Biology, Georgia State University, Atlanta, GA.

1996-1998 Postdoctoral associate, Department of Molecular Biophysics and Biochemistry, Yale University School of Medicine, New Haven, CT.

1998-2000 Principal Investigator, Department of Anti-infectious Diseases, Bristol-Myers Squibb Pharmaceutical Research Institute, Wallingford, CT.

2000- Research Scientist, Division of Infectious Diseases, Wadsworth Center, New York State Department of Health, Albany, NY.

2001- Assistant Professor (2001-2005), Associate Professor (2006-), Department of Biomedical Sciences, School of Public Health, State University of New York-Albany, NY.

Other Experience and Profession Services

2003- Reviewer for Journal of Virology, Virology, Journal of General Virology, and Journal of Clinical Microbiology

2003-2004 *Ad Hoc* reviewer, NIH Special Study Section on Bioterrorism and Emerging Infectious Diseases

2004 Member, NIH Bioshield Study Section

2004 *Ad Hoc* reviewer for grants sponsored by US Civilian Research and Development Foundation

2006- *Ad Hoc* reviewer, NIH Special Study Section on Viral and Eukaryotic Special Emphasis Panel

2007- Editorial Board of Virology

B. Selected peer-reviewed publications (in chronological order)

Peer-reviewed Publications

1. Zhong, S.-D., Nolan, W.G., and **Shi, P.-Y.** 1993. Temperature-induced changes in photosynthetic activities and thylakoid membrane properties of *Euglena gracilis. Plant Science* 92, 121-127.
2. **Shi, P.-Y.**, Brinton, M.A., Veal, J.M., Zhong, Y.Y., and Wilson, W.D. 1996. Evidence for the existence of a pseudoknot structure at the 3' terminus of the flavivirus genomic RNA. *Biochemistry* 35, 4222-4230.
3. **Shi, P.-Y.**, Li, W., and Brinton, M.A. 1996. Cell proteins bind specifically to West Nile virus minus-strand 3' stem-loop RNA. *J. Virol.* 70, 6278-6287.
4. **Shi, P.-Y.**, Sklyarevskaya, T., Kebbekus, P., Brinton, M.A., and Wilson, W.D. 1997. Analysis of the structure and folding of the 3' genomic RNA of flaviviruses. *Nucleic Acids Symp. Ser.* 36, 52-55.
5. **Shi, P.-Y.**, Maizels, N, and Weiner, A.M. 1997. Recovery of soluble, active recombinant protein from inclusion bodies. *BioTechniques* 23, 1036-1038.
6. Brinton, M.A., Kurane, I., Mathew, A., Zeng, L., **Shi, P.-Y.**, Rothman, A., Ennis, F.A. 1998. Immune mediated and inherited defenses against flaviviruses. *Clin. Diagn. Virol.* 10, 129-139.

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9. Maizels, N., Weiner, A.M., Yue, D., and **Shi, P.-Y.** 1999. New Evidence for the genomic tag hypothesis: *Archael* CCA-adding enzyme and tDNA substrates. *Biol. Bull.* 196, 331-334.
10. Bernard, K.A., Maffei, J.G., Jones, S.A., Kauffman, E.B., Ebel, G.D., Dupuis II, A.P., Ngo, K.A., Nicholas, D.C., Young, D.M., **Shi, P.-Y.**, Eidson, M., White, D.J., Stone, W.B., and Kramer, L.D. 2001. Comparison of West Nile virus infection in birds and mosquitoes in New York State in 2000. *Emerg. Infect. Dis.* 7, 679-685.
11. G.D., Ebel, Dupuis II, A.P., Ngo, K.A., Nicholas, D.C., Kauffman, E.B., Jones, S.A., Young, D.M., Maffei, J.G., **Shi, P.-Y.**, Bernard, K.A., and Kramer, L.D. 2001. Partial genetic characterization of WNV strains isolated in New York State during the 2000 transmission season. *Emerg. Infect. Dis.* 7, 650-653.
12. **Shi, P.-Y.**, Kauffman, E.B., Ren, R., Felton, A., Tai, J.H., Dupuis II, A.P., Jones, S.A., Ngo, K.A., Nicholas, D.C., Maffei, J., Ebel, G.D., Bernard, K.A., and Kramer, L.D. 2001. High throughput detection of West Nile virus RNA. *J. Clin. Microbiol.* 39, 1264-1271.
13. **Shi, P.-Y.**, Tilgner, M., Lo, M.K., Kent, K.A. and Bernard, K.A. 2002. An infectious cDNA clone of the epidemic West Nile virus from New York City. *J. Virol.* 76, 5847-6856.
14. **Shi, P.-Y.**, Tilgner, M., and Lo, M.K. 2002. Construction and characterization of subgenomic replicons of New York strain of West Nile virus. *Virology* 296, 219-233.
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17. Lo, M.K., Tilgner, M., Bernard, K.A., and **Shi, P.-Y.** 2003. Functional analysis of mosquito-borne flavivirus conserved sequence elements within 3' untranslated region of West Nile virus using a reporting replicon that differentiates between viral translation and RNA replication. *J. Virol.* 77, 10004-10014.
18. Lo, M.K., Tilgner, M., and **Shi, P.-Y.** 2003. A potential high-throughput assay for screening inhibitors of West Nile virus replication *J. Virol.* 77, 12901-12906.
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21. Tilgner, M. and **Shi, P.-Y.** 2004. Structure and function of the 3' terminal six nucleotides of West Nile virus genome in viral replication *J. Virol.* 78, 8159-8172.
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23. Liu, W.J., Wang, X.J., Mokhonov, V.V., **Shi, P.-Y.**, Randall, R., and Khromykh, A.A. 2005. Inhibition of interferon signaling by New York 99 strain and Kunjin subtype of West Nile virus involves blocking STAT1 and STAT2 activation by nonstructural proteins. *J. Virol.* 79, 1934-1942.
24. Deas, T.S., Binduga-Gajewska I., Tilgner M., Ren P., Stein, D.A., Moulton, H.M., Iversen, P.L., Kauffman, E.B., Kramer, L.D., and **Shi, P.-Y.** 2005. Inhibition of flavivirus infections by antisense oligomers specifically suppressing viral translation and RNA replication. *J. Virol.* 79, 4599-4609.

25. Zhang, C., Cai, Z., Kim, Y.-C., Kumar, R., Yuan, F., **Shi, P.-Y.**, Kao, C., and Luo, G. 2005. Stimulation of the hepatitis C virus NS3 helicase by NS3 protease domain and RNA-dependent RNA polymerase. *J. Virol.* 79, 8687-8697
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C. Research Support

Contract N01-AI-25490 09/30/02-09/29/09
NIH/NIAID
PI: Laura Kramer
Role: Co-Investigator
West Nile and Pox viruses: ecology, pathogenesis and immunology
This is a multi-investigator contract to study the ecology, pathogenesis, and immunology of West Nile and Pox viruses. The scope of this contract includes development of more sophisticated diagnosis, studies of viral transmission cycle, viral pathogenesis, and immunology.

U01 AI061193-01 06/01/04-05/31/09
NIH/NIAID
Role: PI
Identifying Inhibitors of West Nile and Dengue Viruses
This grant is focused on identifying novel inhibitors against West Nile and dengue virus replication through high-throughput screening of compound libraries.

1R43AI065156-01 05/01/05-03/31/07
NIH/NIAID
PI: Patrick Iversen (AVI BioPharma Inc.)
Role: Co-Investigator
Antisense Antiviral Agents for West Nile Virus Infection
This is a SBIR grant to develop antisense agents of West Nile virus infection and to study the mechanism of action of the inhibitors.

1 R21 AI065562-01 07/01/05-06/30/07
NIH/NIAID
Role: PI
West Nile virus life cycle in flavivirus-resistant cells
This grant is proposed to characterize the molecular mechanism of flavivirus resistance.